

WHAT IS CLAIMED IS:

1. A process for making high purity torsemide modification II comprising the steps of:
- (a) adding torsemide modification I to a solvent mixture comprising acetonitrile and water;
 - (b) isolating torsemide modification I;
 - (c) suspending the torsemide modification I of step (b) in water to form a solution;
 - (d) adjusting the solution of step (c) to a pH of about 10 ± 0.2 ;
 - (e) filtering the solution of step (d);
 - (f) adjusting the solution of step (e) to a pH of 6.25 ± 0.2 ; and
 - (g) isolating high purity torsemide modification II.
2. A stable pharmaceutical formulation comprising an effective amount of torsemide modification II and a pharmaceutically acceptable excipients wherein the excipients have a low moisture content.
3. The stable pharmaceutical formulation of claim 2 further comprising the excipients having a low moisture content selected from the group consisting of lactose anhydrous, crospovidone, povidone, microcrystalline cellulose, and magnesium stearate.
4. The stable pharmaceutical formulation of claim 2 comprising torsemide modification II in an amount of about 2.5 mg to about 200 mg per tablet.
5. The stable pharmaceutical formulation of claim 4 comprises torsemide modification II in an amount of about 2.5 mg, about 5 mg, about 10 mg, about 20 mg or about 100 mg per tablet.
6. A stable pharmaceutical formulation comprising an effective amount of torsemide modification II wherein the torsemide modification II does not substantially rearrange into another form of torsemide over time upon storage.

7. The stable pharmaceutical formulation of claim 6 wherein the formulation is stored under stress conditions.

8. The stable pharmaceutical formulation of claim 7 wherein the formulation is stored at about 40°C and about 75% relative humidity.

9. The stable pharmaceutical formulation of claim 6 wherein the torsemide modification II does not substantially rearrange into torsemide modification I over time upon storage under stress conditions.

10. The stable pharmaceutical formulation of claim 9 wherein not more than 5% of the torsemide modification II rearranges into torsemide modification I.

11. The stable pharmaceutical formulation of claim 6 wherein the torsemide modification II is selected from the group consisting of high purity torsemide modification II and torsemide modification II containing trace amounts of torsemide modification I.

12. The stable pharmaceutical formulation of claim 11 wherein the torsemide modification II comprises about 0.5 to about 2% (w/w) of torsemide modification I.

13. The stable pharmaceutical formulation of claim 6 wherein the torsemide modification II has a particle size distribution such that 100 % is below 200 μ .

14. The stable pharmaceutical formulation of claim 13 wherein the particle size distribution is such that 100% is below 100 μ .

15. The stable pharmaceutical formulation of claim 14 wherein the particle size distribution is such that 100% is below 50 μ .

16. High purity torsemide modification II.

17. The high purity torsemide modification II of claim 16 which is a stable polymorphic form of torsemiide.

18. The high purity torsemide modification II of claim 17 which does not substantially rearrange over times.

19. The high purity torsemide modification II of claim 18 further characterized by being stable during storage under stress conditions for at least 3 months.

20. The high purity torsemide modification II of claim 18 which is in the form of fine crystal.

21. The high purity torsemide modification II of claim 18 wherein the high purity torsemide modification II does not substantially rearrange over time into torsemide modification I.

22. The high purity torsemide modification II of claim 21 wherein not more than 10% of the high purity torsemide modification II rearranges over time into torsemide modification I.

23. The high purity torsemide modification II of claim 17 which is further characterized by having a particle size distribution such that 100 % is below 200 μ .

24. The high purity torsemide modification II of claim 23 which is further characterized by having a particle size distribution such that 100% is below 100 μ .

25. The high purity torsemide modification II of claim 24 which is further characterized by having a particle size distribution such that 100% is below 50 μ .

26. High purity torsemide modification II produced according to the process of claim 1.

27. The high purity torsemide modification II of claim 26 which is a stable polymorphic form of torsemide.

28. The high purity torsemide modification II of claim 27 which does not substantially rearrange over times.

29. The high purity torsemide modification II of claim 28 further characterized by being stable during storage under stress conditions for at least 3 months.

30. The high purity torsemide modification II of claim 28 which is in the form of fine crystal.

31. The high purity torsemide modification II of claim 28 wherein the high purity torsemide modification II does not substantially rearrange over time into torsemide modification I.

32. The high purity torsemide modification II of claim 31 wherein not more than 10% of the high purity torsemide modification II rearranges over time into torsemide modification I.

33. The high purity torsemide modification II of claim 32 which is further characterized by having a particle size distribution such that 100 % is below 200 μ .

34. The high purity torsemide modification II of claim 33 which is further characterized by having a particle size distribution such that 100% is below 100 μ .

35. The high purity torsemide modification II of claim 34 which is further characterized by having a particle size distribution such that 100% is below 50 μ .